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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,780	07/26/2001	Ham-Jing Terng	12674-003001	6948

26161 7590 12/03/2003

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BOSTON, MA 02110

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/915,780	TERNG ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/22/2003 has been entered.

Following entry the amendment filed 7/7/2003, the claims 1-36 are pending. Claims 10-22 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 5 and 9 are vague and indefinite because it is unclear whether the binding member is the first or the second binding member since there is a specific binding pair which has a first binding member and a second binding member. Clarification is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 6-8, 23-26, 30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drazen et al. (6,156,503) in view of Ugozzoli et al. (DATA, 1992, Vol. 9(4), pg. 107-112).

Drazen et al. disclose a method and kit of identifying individuals at risk for an adverse response to β -agonist therapy (See column 1, lines 51-54). The method involves using allelic specific primer which has the same structure as the structure of the claimed discrimination primer (See column 11, lines 12-26) except the primer of Drazen et al. does not comprise a binding member covalently bonded to the 5' end of the primer. The primer of Drazen et al. has a mismatch at penultimate position from the 3' end (See column 11, lines 17-26) and a segment of

nucleotide located immediately 5' to the second base is complementary to a part of target nucleic acid (the nucleic acid) (See column 11, lines 17-26).

Drazen et al. also disclose a kit to include primer set capable of amplifying and distinguish the allele specific gene (See column 4, lines 25-35).

Drazen et al. do not disclose that the primer comprises a binding member of a specific binding pair covalently bonded to the 5' end of the primer and the binding member is an oligonucleotide which is not complementary to any part of the nucleic acid.

Ugozzoli et al. disclose a method for determining whether a particular nucleic acid sequence is present in a sample. The method applies an allele-specific primer which has 5' portion complementary to a different preselected nucleic acid sequence (See pg. 107, column 1, the abstract). The 5' portion is an oligonucleotide 6 to 50 nucleotides in length (See pg. 110, fig. 1). And there is an capturing nucleic acid sequence immobilized on the solid support (See pg. 110, fig. 1)

The limitations of claim 1 is interpreted as there are a first binding member of a specific binding pair located at 5' terminus which is the same as the 5' portion of the primer of Ugozzoli et al. (See pg. 107, column 1, the abstract) and a second binding member affixed on a solid substrate which is the same capturing nucleic acid sequence immobilized on the solid support of Ugozzoli et al. (See pg. 110, fig. 1). Therefore, the teachings of Drazen et al. in view of Ugozzoli et al. suggest the limitations of instant claims.

One of ordinary skill in the art would have been motivated to modify the primer of Drazen et al. by applying the 5' portion of the primer of Ugozzoli et al. for making an discrimination primer for amplifying a first base at a position suspected of a polymorphism and

a second base immediately 3' to the first base. The motivation is that by using the binding member of a specific binding pair at 5' end of the primer, it allows the primer-extension product to be immobilized on a solid support by hybridization and it makes the method more specific and offers a valid alternative to study DNA polymorphism (See pg. 111, column 2, third paragraph). It would have been prima facie obvious to make the primer having a first binding member included in a specific binding pair located at the 5' portion which is not complementary to any part of the nucleic acid.

6. Claims 5, 9, 27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drazen et al. (6,156,503) in view of Ugozzoli et al. (DATA, 1992, Vol. 9(4), pg. 107-112) as applied to claims 1-4, 6-8, 23-26, 30 and 32-36 above, and further in view of Drmanac et al. (6,383,742, issued May 7, 2002).

The teachings of Drazen et al. and Ugozzoli et al. are set forth in section 5 above. Drazen et al. and Ugozzoli et al. do not disclose the binding member which is peptide and the primer is labeled.

Drmanac et al. disclose a method of detecting a target nucleic acid species involving using labeled probe (See the Abstract). The label can be ligands which can serve as specific binding members to a labeled antibody, chemilumescers, enzymes, antibodies which can serve as a specific binding pair member for a labeled ligand (See column 18, lines 64-67 to column 19, lines 1-4). The antibodies and enzymes are peptide.

Therefore one of ordinary skill in the art would have been motivated to modify the primer of Drazen et al. by applying the antibody as a binding member as taught by Drmanac et al. (See column 18, lines 64-67 to column 19, lines 1-4 and column 22, lines 1-14) at 5' terminus of the

primer. The motivation is that by using the binding member of a specific binding pair at 5' end of the nucleic acid primer, a small number of nucleic acid sample can be fast identified (See column 6, lines 64-67). It would have been prima facie obvious to make the discrimination primer with a peptide binding member at 5' terminus.

Summary

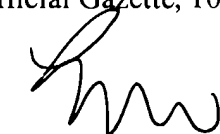
7. No claims are allowable.
8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung J.T.
November 20, 2003



ETHAN WHISENANT
PRIMARY EXAMINER